

Hans Boehringer et al.
Application No.: 08/812,616
Page 2

1 10. (Amended) [The] A method of [claim 1,] visually quantifying an
2 amount of an analyte in a sample, wherein the analyte is a member of a specific binding pair
3 (sbp member), comprising:
4 providing a lateral flow matrix which defines a flow path and which comprises
5 in series, a sample receiving zone, a labeling zone, and one or more serially oriented capture
6 zones, wherein the labeling zone comprises a diffusively bound labeled first sbp member that
7 is complementary to or analogous to the analyte, and each of the one or more capture zones
8 comprises at least a second sbp member immobilized in the capture zone, the second sbp
9 member being complementary to the analyte;
10 contacting the sample with the sample receiving zone, whereby the sample
11 flows along the flow path;
12 observing a pattern of label that accumulates at the one or more capture zones;
13 and
14 correlating a pattern of label accumulated in the one or more capture zones to
15 the amount of analyte in the sample;
16 wherein the second sbp member is an antibody against a complex formed
17 between the analyte and the first sbp member.

1 15. (Amended) [The] A method of [claim 1,] visually quantifying an
2 amount of an analyte in a sample, wherein the analyte is a member of a specific binding pair
3 (sbp member), comprising:
4 providing a lateral flow matrix which defines a flow path and which comprises
5 in series, a sample receiving zone, a labeling zone, and one or more serially oriented capture
6 zones, wherein the labeling zone comprises a diffusively bound labeled first sbp member that
7 is complementary to or analogous to the analyte, and each of the one or more capture zones
8 comprises at least a second sbp member immobilized in the capture zone, the second sbp
9 member being complementary to the analyte;
10 contacting the sample with the sample receiving zone, whereby the sample
11 flows along the flow path;
12 observing a pattern of label that accumulates at the one or more capture zones;
13 and

Hans Boehringer et al
Application No.: 08/812,616
Page 3

14 correlating a pattern of label accumulated in the one or more capture zones to
15 the amount of analyte in the sample;

16 wherein the sample receiving zone comprises an amount of a third sbp member
17 immobilized within the sample receiving zone and complementary to the analyte, the amount
18 being sufficient to bind a threshold level of the analyte.

1 23. (Amended) [The] A method of [claim 18,] determining an amount of
2 an analyte in a sample, wherein the analyte is a member of a specific binding pair (sbp
3 member), comprising:

4 providing a lateral flow matrix which defines a flow path and which comprises
5 in series, a sample receiving zone, a labeling zone, and one or more serially oriented capture
6 zones, wherein the labeling zone comprises a diffusively bound labeled first sbp member that
7 is complementary to the analyte, and each of the one or more capture zones comprises at least a
8 second sbp member immobilized in the capture zone, the second sbp member being analogous
9 to the analyte;

10 contacting the sample with the sample receiving zone, whereby the sample
11 flows along the flow path;

12 observing a pattern of labeled first sbp member that accumulates at the one or
13 more capture zones; and

14 correlating a pattern of label accumulated in the one or more capture zones to
15 the amount of analyte in the sample;

16 wherein the labeled first sbp member includes a visually detectable label;

17 wherein the sample receiving zone comprises an amount of a third sbp member
18 immobilized within the sample receiving zone and complementary to the analyte, the amount
19 being sufficient to bind a threshold level of the analyte.

1 In claim 53, lines 9-10, after the words "complementary to", delete the words
2 "or analogous to".

1 In claims 56-57, change the claim dependencies from "claim 55" to --
2 claim 53--.

Hans Boehringer et al
Application No.: 08/812,616
Page 5

7 one or more serially oriented capture zones;
8 wherein the labeling zone comprises a diffusively bound labeled first sbp
9 member that is complementary to or analogous to the analyte, and each of the one or more
10 capture zones comprises at least a second sbp member immobilized in the capture zone, the
11 second sbp member being complementary to the analyte;
12 wherein the sample receiving zone comprises an amount of a third sbp member immobilized
13 within the sample receiving zone and complementary to the analyte, the amount being
14 sufficient to bind a threshold level of the analyte.

1 In claim 71, change the dependency from "claim 72" to --claim 70--.

1 In claims 73 and 74, change the claim dependencies from "claim 74" to --claim
2 72--.

1 In claim 75, change the claim dependency from "claim 76" to --claim 74--.

1 In claims 76-78, and 80, change the claim dependencies from "claim 74" to --
2 claim 72--.

1 79. (Amended) [The] A device [of claim 74,] for determining an amount of
2 an analyte in a sample, wherein the analyte is a member of a specific binding pair (sbp
3 member), the device comprising a lateral flow matrix which defines a flow path and which
4 comprises in series:

5 a sample receiving zone;

6 a labeling zone; and

7 one or more serially oriented capture zones;

8 wherein the labeling zone comprises a diffusively bound labeled first sbp member that is
9 complementary to the analyte, and each of the one or more capture zones comprises at least a
10 second sbp member immobilized in the capture zone, the second sbp member being analogous
11 to the analyte;

Hans Boehringer et al.
Application No.: 08/812,616
Page 6

12 wherein the sample receiving zone comprises an amount of a third sbp member immobilized
13 within the sample receiving zone and complementary to the analyte, the amount being
14 sufficient to bind a threshold level of the analyte.

1 In claim 81, change the claim dependency from "claim 82" to --claim 80--.

1
2 120. (Amended) A kit for determining an amount of an analyte in a sample,
3 wherein the analyte is a member of a specific binding pair (sbp member), the kit comprising
4 the device of [any one of] claim[s 55,] 53 [74, 84, 98 or 110], a chart for correlating an
5 observed accumulation of label at the one or more capture zones, to a concentration of analyte
6 in a sample applied to the sample receiving zone, and instructions for using the device.

1
2 Please add new claims 121-125 as follows:

--121. (New) A kit for determining an amount of an analyte in a sample,
wherein the analyte is a member of a specific binding pair (sbp member), the kit comprising
the device of claim 74, a chart for correlating an observed accumulation of label at the one or
more capture zones, to a concentration of analyte in a sample applied to the sample receiving
zone, and instructions for using the device.

1
2 122. (New) The device of claim 53, wherein the first sbp member is a ligand
3 and the second sbp member is a receptor complementary to the ligand.--

1
2 123. (New) The device of claim 121 wherein the ligand is a hapten and the
3 receptor is a complement to the hapten.

1 124. (New) A method of visually quantifying an amount of an analyte in a
2 sample, wherein the analyte is a member of a specific binding pair (sbp member), comprising:
3 providing a lateral flow matrix which defines a flow path and which comprises
4 in series, a sample receiving zone, a labeling zone, and one or more serially oriented capture
5 zones, wherein the labeling zone comprises a diffusively bound labeled first sbp member that